IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ALL WAVE 5 CASES AND THOSE ON ATTACHED EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION
TO EXCLUDE CERTAIN OPINIONS OF DR. RAGNVALD MJANGER

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' Obstetrician-Gynecologist and Female Pelvic Medicine and Reconstructive Surgery expert Ragnvald Mjanger, M.D. ("Dr. Mjanger"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Mjanger is board certified in Obstetrics and Gynecology and certified in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery. Exhibit B, Mjanger CV, p. 1. Plaintiffs do not challenge his qualifications as such. However, Dr. Mjanger seeks to offer testimony that is not helpful for the jury, clearly exceeds the bounds of his qualifications, and is founded on insufficient facts and unreliable methodology.[1] Specifically, this Court should exclude Dr. Mjanger's opinions regarding: (1) the adequacy of Defendants' product warnings and instructions for use ("IFU"), including opinions regarding what risks of the devices other

[1] *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

doctors know of; (2) whether Defendants' transvaginal mesh products at issue are defectively or reasonably designed; (3) the degradation of polypropylene or its clinical significance; and (4) his statements about the safety and efficacy of Defendants' products based on his own practice.

LEGAL STANDARD

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by "knowledge, skill, experience, training or education." Fed. R. Evid. 702. The witness's testimony also must represent "scientific knowledge," meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. Opinion evidence may be admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. In the end, an expert's testimony is admissible if it "rests on a reliable foundation and is relevant." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Mjanger to proffer expert testimony and "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Maryland Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Mjanger is qualified and his testimony is reliable, "testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig*., 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15,2014)

reconsideration denied, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, his testimony must "fit" the case, and there must be a "valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id*.

ARGUMENT

This Court should prohibit Dr. Mjanger from giving the opinions referenced above because he is not qualified to opine on those issues, applies a flawed methodology and standard for arriving at his opinions, and has not done the necessary research to produce opinions that can reliably be applied to this case.

1. **Dr. Mjanger's opinions on the adequacy of Defendants' warnings should be excluded pursuant to *Daubert*.**

Dr. Mjanger's opinions on the adequacy of Defendants' warnings are based on precisely the *ipse dixit* that the Supreme Court has found inadmissible. Dr. Mjanger admits he is wholly unaware of the applicable FDA standards governing what risk information medical device companies are required to put in IFUs. He admits that his opinions on the adequacy of defendants' warnings are based on nothing more than personal convictions regarding what risks are commonly known to physicians about the device. He admits he performed no independent research at all on standards of any kind before publishing his expert report. Finally, he admits that has never engaged in any formal analysis or study to see what risks of the TVT or TVT-O were known to physicians who implant those devices, despite opining that the IFUs for each are adequate in providing this information to intended users. Such testimony lies at the heart of what *Daubert* and its progeny have found inadmissible.

This Court exercises its "gatekeeping" function to ensure that expert testimony is both relevant and reliable. FED. R. EVID. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (*citing Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). This obligation

applies to all types of expert testimony, not merely scientific analysis. *Kumho Tire*, 526 U.S. at 149; *Holsesapple v. Barrett*, No. 00-1537, 2001 WL 208490, at *1 (4th Cir. 2001). While an expert urologist or pelvic floor surgeon may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Mjanger does not possess the additional expertise to offer expert testimony about what an IFU should or should not include, and therefore his testimony regarding these issues should be excluded.

Dr. Mjanger relies solely on his personal convictions in opining that the IFU adequately inform users about the potential risks of the TVT and TVT-O to pelvic floor surgeons who perform SUI surgery. Exhibit C, Mjanger TVT and TVT-O report, p. 12. Dr. Mjanger admits he is not an expert on warnings of medical devices and is unaware of the applicable FDA standards governing what risk information medical device companies are required to put in IFUs:

> Q. And I'm correct that you don't' know what the FDA requirements are regarding warnings for medical devices?
>
> A. Correct. [2]

Dr. Mjanger is not an expert on what risk information medical device manufacturers are required to put in IFUs.[3] He has never written an IFU.[4] He is not an expert on FDA regulations or device warnings.[5] In addition, he admits that he does not have the regulatory or legal background required to interpret such a standard.

[2] Dr. Mjanger Dep. Tr., 07-20-2017, 34:16-19; Plaintiff's Motion, Exhibit D.
[3] *Id.* at 33:14-18.
[4] *Id.* at 34:20-22.
[5] *Id.* at 34:16-19.

Dr. Mjanger states in his report that he is familiar with physicians' use of and reliance on IFUs, [6] and uses this as part of the basis for his opinion that the IFUs are adequate. However, Dr. Mjanger has never done a survey or used any formal methodology to determine what physicians do or do not know with regard to the pelvic mesh devices.[7] He has never done any kind of formal analysis to determine what percentage of mesh users knew, for example, that pain or chronic pain was a potential risk of the pelvic mesh devices. Dr. Mjanger states that he has seen patients with temporary pain due to pelvic mesh devices but never chronic pain.[8] This is yet another example of Dr. Mjanger using his personal observations without any formal methodology to form opinions regarding the adequacy of the IFU for the TVT and TVT-O. Since Dr. Mjanger is relying on what physicians commonly knew about the risks of the devices as a component of his opinion that the IFUs were adequate—yet he cannot state what percentage of physicians knew about particular risks—then he cannot testify reliably as to whether the IFUs were adequate. His opinion is not grounded on any objective evidence. Rather Dr. Mjanger simply provides his own *ipse dixit* to support his opinions.

Dr. Mjanger's opinions that physicians knew all the risks of the pelvic mesh devices appear to be based on his personal conviction that any doctor who reads a core textbook in urology or gynecology knows of the risks of complications from the pelvic mesh. However, he has no objective evidence for this conclusion, and it is purely speculation, as he has conducted no inquiry into what risks doctors who use the pelvic mesh devices actually know. Dr. Mjanger's testimony on the adequacy of Defendants' warnings should be excluded because it is based on no objective criteria, but instead, on Dr. Mjanger's personal belief that all surgeons have reviewed and retained information in certain textbooks and other materials.

[6] Ex. C, at p. 12.
[7] Ex. D, at 227:15-228:6.
[8] *Id.* at 129:16-23.

Federal courts agree that *ipse dixit* opinions—which are justified solely by the fact that the expert holds them—are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong.").

To be admissible, expert testimony must explain the link between the available evidence or data and the expert's opinion. *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2001); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at *9 (S.D. Ind. Apr. 19, 2007) ("It is not enough for an expert to say this is my data and that is my conclusion without connecting the two."); *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1390 (7th Cir. 1989) ("An opinion has a significance proportioned to the sources that sustain it.").

Dr. Mjanger has never read any testimony of Ethicon or Johnson & Johnson employees regarding Ethicon's position or policies on what needs to be in an IFU with regard to risk information.[9] It is clear from his testimony that he does not know what standards apply to the IFU for a medical device, nor how to apply those standards. Further, it is unknown what materials Dr. Mjanger reviewed or did not review from his reliance list, as Dr. Mjanger testified that his reliance list contains materials that he did not actually review.[10] Further, he testified that his reliance list was mostly put together by counsel for Ethicon and not himself prior to it being served.[11] This violates F.R Civ. P 26(a)(2)(B)(ii), and leaves Plaintiffs with an incomplete understanding of the facts and materials Dr. Mjanger utilized to support his opinions. Given that Dr. Mjanger's testimony indicates that he did not actually review or rely on any objective

[9] *Id.* at 33:23-34:4, 34:10-15.
[10] *Id.* at 14:22-15:8, 15:20-16:2
[11] *Id*. at 15:9-19.

standard for his opinions that the pelvic mesh IFUs are inadequate, the Court should prohibit this opinion under *Daubert*.

II. Dr. Mjanger should be precluded from giving design opinions.

a. Dr. Mjanger has expressly testified that he is not a design expert and does not know the standards for designing a pelvic mesh product.

As a primary issue, Dr. Mjanger should be precluded from opining about the design of the subject products. Specifically, he should be precluded from offering any opinions regarding whether or not the subject products are defectively designed. Dr. Mjanger admits he is not an expert on design of medical devices or pelvic mesh products and has no opinion regarding the design:

Q. Do you hold yourself out as an expert in the design of pelvic mesh products?

A. No.

Q. So, I take it, then, that you don't know what standards a manufacturer must follow in designing a mesh product like the TVT or TVT-O?

A. Correct.[12]

This Court has previously recognized the importance of an expert's admission that he is not an expert. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Mjanger, who admitted he is not an expert on design of the mesh products—nor is he even knowledgeable of the standards in designing the mesh products. As such, he should be precluded from giving any opinions related

[12] *Id*. at 36:7-14

to the design of the subject products, including whether or not the products are designed in a reasonable manner.

b. Dr. Mjanger did not review Defendants' key documents related to product design, and even if he had reviewed them, Dr. Mjanger has no base knowledge as to what those documents would demonstrate.

Dr. Mjanger should also be precluded from opining about the design of the subject products because has not reviewed Defendants' internal documents about the design process. This issue was central to the exclusion of design opinions by a urogynecologist for the plaintiffs in the *Boston Scientific Litigation*. Boston Scientific Corp. ("BSC") moved to exclude Dr. Shull because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015). The plaintiffs countered that Dr. Shull had relied on other BSC internal documents, as well as the scientific literature. *Id.*

This Court agreed with BSC and excluded Dr. Shull from giving any opinions about design procedures. This Court reasoned that "regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull's methodology. Without any reliable, demonstrated knowledge of BSC's internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way." *Id.*

The same analysis applies to Dr. Mjanger in this case. He confirmed that he did not review Defendants' design history file, failure modes effects analysis, or any other internal design documents in formulating his opinions:

Q. Do you know what a design history file is?

A. No.

Q. So, I take it, then, that you haven't reviewed the design history file for the TVT or TVT-O in coming to your conclusions in this case?

A. I can't say if I reviewed it, because I don't know what – what –

Q. Do you know what a failure modes effects analysis is?

A. No.

Q. Do you know what a design modes effects analysis is?

A. Technical term from a –

Q. I want to know if you know what that term means or not.

A. No, I don't.

Q. To the best of your knowledge, have you ever reviewed any of the failure modes effects analysis, whether it be the design failure modes, the process failure modes, or the application failure modes effects analysis for the TVT or TVT-O device?

A. Where would I see that or find that or get that? I don't – where would that be?[13]

Dr. Mjanger has admitted that he has not reviewed and is not familiar with Ethicon's internal design standard operating procedures related to the design of medical devices.[14] He admitted he does not know what kind of experts Ethicon would need to use in designing a pelvic mesh device.[15]

Further, Dr. Mjanger testified that his opinion regarding the design of the TVT and TVT-O being reasonably safe is based solely on his personal experience using the products and not the design protocols or methodology of a medical device manufacturer:

[13] *Id*. at 37:21-38:21
[14] *Id*. at 36:7-14; 38:23-39-13.
[15] *Id*. at 37:11-15

Q. So you can't articulate any objective standard that you're applying for an acceptable complication rate for the TVT or TVT-O to conclude that the design is reasonably safe for its intended use?

A. That's for a researcher to do that. As far as I'm concerned, the TVT is very, very safe. We put them in a variety of patients with other issues that don't come up here.

***

Q. So, I guess my question is: If you're concluding that the design of the TVT and TVT-O devices is reasonably safe, how would I know a design of an SUI device wasn't reasonably safe?

[def. counsel] Objection

A. You would have to ask people who are in the business of designing them. I'm in the business of using it. I think it's a very safe product, compared to the other option which is far more invasive surgery with its own risks. It may not be a risk of erosion but there are other risks involved.[16]

Since Dr. Mjanger did not review the relevant design documents, and has not done the appropriate analysis with regard to the design of the products, he lacks the required knowledge and foundation to give a reliable opinion about the design and reasonableness of Defendants' transvaginal mesh products, including, but not limited to whether or not the design of the devices was reasonable. Based on the foregoing, all Dr. Mjanger's opinions on the issue of product design should be excluded. As he said, he is not "in the business" of designing products.

[16] *Id*. at 273:10-274:19

III. Dr. Mjanger should be precluded from testifying that polypropylene does not degrade *in vivo*.

Dr. Mjanger seeks to opine that polypropylene mesh does not degrade in vivo.[17] He further opines that if it does, any such degradation has no clinically significant effect and does not lead to recurrence, pelvic pain, or dyspareunia.[18] Dr. Mjanger's opinions regarding the degradation of polypropylene mesh should be excluded.

As an initial matter, Dr. Mjanger's lack of knowledge about the degradation process, and the chemical properties of Prolene, should serve to preclude his so called "expert" opinions on the issue. For example, Dr. Mjanger does not hold himself out as an expert in chemical engineering, pathology, or polymer chemistry.[19] He further testified that he has not done any bench or lab research on polypropylene or polypropylene meshes.[20] Dr. Mjanger also testified that he has never performed any kind of pathological analysis on any explanted polypropylene meshes, and he confirmed that he is not a biomaterials specialist.[21]

Moreover, Dr. Mjanger admitted in his deposition that he does not know enough about degradation to state an opinion regarding its clinical significance.[22] However, an expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation.[23]

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[17] Ex. C at p. 9
[18] *Id.* at 9
[19] Ex. D at 31:16-32:2.
[20] *Id.* at 32:3-8
[21] *Id*. at 32:9-17
[22] *Id.* at 268:9-269:1
[23] *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3 (4th Cir., Sept. 8, 1997); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

IV. Dr. Mjanger's opinions about his personal experience related to the safety and efficacy of the pelvic mesh products should be excluded because they are not based on any objective standard, and his analysis and methodology are flawed.

Dr. Mjanger should be precluded from testifying about his perceived safety, efficacy, and patient satisfactions rates with the subject products from his practice, as those opinions are entirely unsupported by any reliable methodology, nor have they been subject to peer review. This court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable. *In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016).

Dr. Mjanger testified that he intends to opine that his own patients have not experienced a chronic inflammatory response with TVT that resulted in clinical consequences such as pain.[24] However, in arriving at this opinion, Dr. Mjanger admits he has not done any kind of formalized analysis of his patients or his patients' medical records.[25]

Dr. Mjanger's report goes on to state that, in his experience, any inflammation that may occur remains stable, or contained in an area immediately adjacent to the mesh, and does not expand in size.[26] When questioned about the basis for this opinion, Dr. Mjanger confirmed it was based on his personal observations and no reliable methodology:

> Q. It also states in this paragraph that in your experience, "this inflammation remains stable or contained in an area immediately adjacent to the mesh and does not continue to expand in size."
>
> A. That's correct.
>
> Q. What's this opinion based on?

[24] Ex. D at 244:18-245:4
[25] *Id.* at 246:4-11
[26] Ex. C at p. 8

A. The tissue around looks very soft and normal and there's really a mark where the inflammation is and no inflammation. You can really see it.

Q. So this opinion is basically based on what you see in general when you remove meshes?

A. Yes.

Q. If there is inflammation that isn't stable, is that something that you would note in your operative report?

A. If I saw it, yeah.

Q. Have you done any kind of formalized analysis of your patients' records to see if that was actually noted in any of their records?

A. No.

Q. Would you agree that if a pathology report or a formal analysis indicated that the inflammation around the TVT mesh was, in fact, not stable but was chronic and ongoing, would that be an indication to you or a defect or problem with the mesh?

[Objection]

A. I haven't seen that, so I wouldn't be able to make a statement on a case that I recall seeing that.[27]

Dr. Mjanger's opinions about patient satisfaction and adverse event rates among his own patients are inappropriate, unsupported, and inadmissible. His opinions are exactly the kind of foundationless testimony this Court has excluded in the past. He lacks any reliable methodology or analysis to support his conclusions. In addition, allowing Dr. Mjanger to offer an opinion as to his patient satisfaction rate and "significant adverse event rate" for his own patients would be confusing and misleading to a jury when considering whether the mesh devices in question are

[27] Ex. D at 246:19-248:7

defective. Thus, his opinions should be excluded under Rule 403. Because there is no foundation for his opinions, Dr. Mjanger should be prohibited from providing this testimony.

CONCLUSION

Based on the foregoing, Dr. Mjanger should be precluded from giving opinions on: (1) the adequacy of Defendants' product warnings and instructions for use ("IFU"), including opinions regarding what risks of the devices other doctors know of; (2) whether Defendants' transvaginal mesh products at issue are defectively or reasonably designed; (3) the degradation of polypropylene or its clinical significance; (4) his statements about the safety and efficacy of Defendants' products based on his own practice.

Dated: August 15, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system in the individual case of Betty Linton McCumber v. Ethicon, Inc, et al., 2:12-cv-08083. I hereby certify that on August 17, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system in Ethicon MDL #2327, which sent notification of such filing to the CM/ECF participants registered to receive service in this MDL. I hereby certify that on August 18, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF participants registered to receive service in this MDL.

/s/Thomas P. Cartmell